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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/631,011

07/31/2003

Markus Berger

DORRIE-9

9536

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7590

09/29/2005

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/631,011

Applicant(s)

BERGER ET AL.

Examiner

Taofiq A. Solola

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 26 July 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-28 is/are pending in the application.  
4a) Of the above claim(s) 1-8 and 12-28 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) 9-11 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

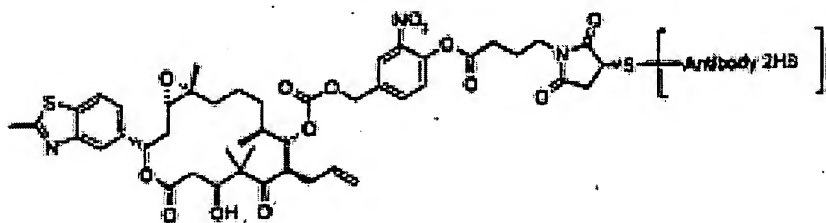
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Claims 1-28 are pending in this application.

Claims 1-8, 12-28 are drawn to non-elected invention.

### ***RESTRICTION REQUIREMENT***

In response to the Restriction Requirement, Applicant elects with traverse the invention of group II, claims 9-11. The traversal is on the basis that the Office has not shown it would be undue burden to examine all the groups. This is not persuasive for reasons set forth in the Restriction Requirement. Applicant also elects the following species:




Therefore, claims 9-11 are being examined in part subject to the election made by applicant.

### ***Status of Claims***

The Office has reviewed the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention encompasses all compounds within the scope of the claims, which fall into the same class and subclass as the elected compound, but may include additional compounds, which fall in related subclasses. Examination of the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification results in the following:

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In formula I, W, R1, R3-R7 and L1-L4 are as defined in claim 1. A-Y is O-C(=O), O-CH<sub>2</sub>, CH<sub>2</sub>-C(=O), NR<sup>21</sup>-C(O); D-E is CH<sub>2</sub>-CH<sub>2</sub>; HC=CH, C≡C, CH(OH)-CH(OH), CH(OH)-CH<sub>2</sub>, CH<sub>2</sub>-CH(OH),  $\text{HC} \overset{\text{O}}{\text{---}} \text{CH}$ ; G and X are each O; one of R2a and R2b is , the other is as defined in claim 1. As a result of the election and the corresponding scope of the invention identified herein, the remaining subject matter of claims 9-11 are withdrawn from further consideration by the Examiner, under 37 CFR § 1.142(b), as being drawn to a non-elected subject matter. The withdrawn compounds are patentably distinct from the examined invention as they differ in structure and element and would require a separate search. In addition, a reference, which anticipates the examined invention, would not render obvious the non-examined subject matter.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is an independent claim but relies on claim 1 for the definitions of its substituents. Also, claim 11 relies on the specification for the contents of Table 1. A claim must stand alone to define the invention, and incorporation into the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608,

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BdPatApp & Inter. (1993). By adding the definitions to claim 9 and the contents of Table 1 to claim 11 the rejection would be overcome.

The term “can”, claim 1, line 4, page 4, and in every occurrence, when read into claim 9 renders claims 9-11 indefinite. The definitions must be cited with definite terms, such as “is”. By deleting the term in every occurrence the rejection would be overcome.

The terms “PG<sup>x</sup>, PG<sup>y</sup> and PG<sup>z</sup> is protective group PG” in claim 1 and “PG<sup>1</sup>, PG<sup>2a</sup>, PG<sup>2b</sup>” in claim 9 renders claims 9-11 indefinite. The protective groups cannot stand alone they must be described with what they protect, i.e. PG<sup>1</sup> is a oxygen- or nitrogen-protective group, etc as the case may be with each protective group.

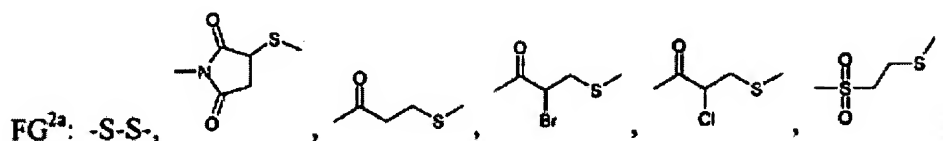
The term “H/OR”, in claim 1, and in every occurrence, when read into claim 9 renders claims 9-11 indefinite. The term is not defined in the specification, not a normal chemical nomenclature and not found in any chemical dictionary. By deleting the term in every occurrence the rejection would be overcome.

Claim 9 is not in proper Markush format due to the presence of the phraseology “as a single isomer or a mixture of different isomers and/or as a pharmaceutically acceptable salt thereof”. By replacing the phraseology with “isomers, mixtures of isomers and pharmaceutically acceptable salts thereof” the rejection would be overcome. In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

The recitation below in claim 9 is confusing and therefore, renders claims 9-11 indefinite. Appropriate correction is required.

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group  $FG^1$  is replaced by a group  $FG^{2a}$  or  $FG^{2b}$ , wherein  $FG^{2a}$  or  $FG^{2b}$  can have the following meanings:



$FG^{2b}$ :  $-CONH-$ ;

and wherein a recognition unit is conjugated via a sulfur atom with the group  $FG^{2a}$  or via an amide function with group  $FG^{2b}$ ; wherein the recognition unit is selected from the group that consists of peptides, soluble receptors, cytokines, lymphokines, aptamers, spiegelmers, recombinant proteins, new framework structures, monoclonal antibodies and fragments of monoclonal antibodies;

### *Allowable Subject Matter*

Claims 9-11 are objected to for containing non-elected subject matter. To place the application in condition for allowance, all claims drawn to non-elected subject matter must be cancelled and the remaining claims must be amended within the scope of allowable subject matter set forth above under Status of Claims.

### *Telephone Inquiry*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

  
**TAOFIQ SOLOLA**  
**PRIMARY EXAMINER**  
Group 1626

September 22, 2005